wherein said polypeptide is over expressed in ovarian cancer relative to normal ovarian tissue.

78. (New) A fusion polypeptide comprising a polypeptide according to any one of claims 73-77.

79. (New) A composition comprising a polypeptide according to any one of claims 73-77 and at least one physiologically acceptable excipient.

80. (New) A composition comprising a polypeptide according to any one of claims 73-77 and at least one adjuvant.

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81. (New) The composition of claim 80, wherein the adjuvant is selected from the group consisting of: an MPL, QS21 and AS-2.

REMARKS

Favorable reconsideration of the subject application is respectfully requested in view of the above amendments and the following remarks. Claims 1, 2, 9-12, 21, 23, 24, and 69 are currently under consideration in this case. Following the amendments, claims 1, 2, 9-12, 21, 23, 24, and 69 are cancelled in favor of newly added claims 73-81. New claims 73-81 are drawn to isolated polypeptides comprising SEQ ID NO:392, polypeptides comprising amino acid residues 1-27 of SEQ ID NO:392, polypeptides having at least 90% identity with SEQ ID NO:392, as well as fusion proteins and compositions thereof. It is urged that support for the above amendments can be found throughout the specification as originally filed (*e.g.*, pg. 18, lines 9-11 and page 53, lines 19-21) and that none of the amendments constitutes new matter.

It should also be noted that the above amendments are not to be construed as acquiescence with regard to the Examiner's rejections, and are made without prejudice to prosecution of any subject matter modified and/or removed by this amendment in a related divisional, continuation and/or continuation-in-part application.

Objection to the Specification

The Examiner's objection to the specification regarding the brief description of the drawings is noted. In reply, applicants submit the above amendments to the specification, incorporating the Examiner's suggestion regarding Figures 10-14, and adding a table label in Example 2. Reconsideration and withdrawal of this objection is therefore respectfully requested.

Rejection Under 35 U.S.C. §101/112 (Utility Rejection)

Claims 1, 2, 9-12, 21, 23, 24, and 69 stand rejected under 35 U.S.C. §101, because the claimed invention allegedly lacks specific, substantial and credible utilities. Specifically, the Examiner alleges that, given the disclosure of the specification, one of ordinary skill in the art would have to perform additional tests to determine whether O8E is an antigen that is diagnostic for ovarian cancer. Applicants respectfully traverse this rejection on the following grounds.

Applicants have identified a specificity associated with the claimed polypeptides, *i.e.,* ovary tumor-specificity, that is more than sufficient to establish utility under 35 U.S.C. §101. In the instant application, a polynucleotide encoding a portion of the claimed polypeptide was found to be over expressed in ovary tumors relative to normal ovarian tissue. For instance, support can be found in Example 1, at page 48, lines 29-30, which discloses that microarray analysis identified clone 13695, also referred to as O8E (SEQ ID NO:74), as an ovarian tumor-associated sequence. Moreover, the microarray results, as set forth in Figure 3, clearly establish that this sequence is expressed in ovarian tumor samples at higher levels than in normal ovarian tissue. As further disclosed in Example 2, at page 53, lines 7-21, this clone was found to be contained within an extended sequence, SEQ ID NO:391, which encodes the polypeptides of SEQ ID NOs: 392 and 393.

As expected based on this ovary tumor-associated mRNA expression profile, the encoded O8E polypeptide has also been demonstrated by the applicants to be over expressed in ovarian tumors. For example at page 55, lines 12-17, the specification describes that O8E protein was detected, by immunohistochemical (IHC) analysis, in 1/6

papillary serous carcinoma samples stained using polyclonal antibodies specific for O8E. Furthermore, monoclonal antibodies against the polypeptide of the claimed invention have been generated by the applicants and optimized for additional IHC analysis of various ovarian tumors and normal ovary tissues. These studies, as set forth in the attached Declaration of Gary Fanger, Ph.D., confirm that SEQ ID NO:392 is expressed in the majority of ovarian tumors tested, but is not expressed in normal ovarian tissue, consistent with the cDNA microarray results described in Example 1 and Figure 3, and consistent with the IHC data of Example 4.

Thus, in view of the description in the applicants' specification as originally filed, and as further confirmed by the attached Declaration of Gary Fanger, Ph.D., applicants submit that one of ordinary skill in the art would fully recognize that SEQ ID NO: 392 has diagnostic utility on the basis of its ovary-tumor specific expression profile. Reconsideration and withdrawal of the rejection is respectfully requested.

Rejections Under 35 U.S.C. §112, first paragraph

The Examiner rejects claims 1 and 2 and claims 9-12, 21, 23, and 24 dependent therefrom, under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, the Examiner alleges that the specification, as filed, does not identify which portions of the polypeptide of SEQ ID NO:392 would be likely to have antigenic sites such that they could bind to an antibody specific for SEQ ID NO:392.

As set forth in the above amendment, applicants have elected to cancel claims 1, 2, 9-12, 21, 23, and 24 at this time, without prejudice, in favor of newly added claims 73-81. Claims 74-77, and claims 78-81 dependent therefrom, now contain the functional recitation "wherein said polypeptide is over expressed in ovarian cancer relative to normal ovarian tissue." Support for this amendment can be found throughout the applicants' specification as originally filed (*e.g.*, page 7, lines 22-24 and page 8, lines 5-8). As discussed above in the context of the Examiner's rejection under 35 U.S.C. §101 rejection, the instant specification offers ample support that SEQ ID NO:392

represents a polypeptide that is expressed in ovarian cancer but not in normal ovary tissue. The skilled artisan, in view of this disclosure, would readily understand how to make and use the presently claimed compositions using only routine and art-recognized methodologies. Reconsideration and withdrawal of the Examiner's rejection is thus respectfully requested.

The Examiner also rejects claims 9-12, 23 and 24 under 35 U.S.C §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, the Examiner alleges that the claims are drawn to pharmaceutical compositions and vaccine compositions, which are not enabled in the specification. As set forth in the above amendment, applicants have elected to cancel claims 9-12, 23, and 24 at this time, without prejudice, in order to advance prosecution of this application to allowance. Applicants, however, specifically reserve the right to pursue the same or similar subject matter in a related application.

Claims 1, 2, 9-12, 21, 23, and 24 stand rejected under 35 U.S.C §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, were in possession of the claimed invention.

As set forth in the above amendment, applicants have elected to cancel claims 1, 2, 9-12, 21, 23, and 24 at this time, without prejudice, in favor of newly added claims 73-81. New claims 73-81 are drawn to isolated polypeptides comprising SEQ ID NO: 392, polypeptides comprising amino acid residues 1-27 of SEQ ID NO: 392, and polypeptides having at least 90% identity with SEQ ID NO: 392, wherein said polypeptide is over expressed in ovarian cancer relative to normal ovarian tissue.

The U.S.P.T.O. has indicated that possession of an invention is more readily established, and correspondingly greater claim breadth is permissible, where an applicant discloses functional and/or descriptive information concerning the specie(s) in an application, e.g., a distinguishing identifying characteristic common among the

members of a claimed genus (see *Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, para. 1, "Written Description" Requirement* – Federal Register: January 5, 2001 (Volume 66, No. 4, pgs. 1099-1111). For example, at the bottom of pg. 1105, the *Guidelines* state that, "(a)n adequate written description of the invention may be shown by any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention."

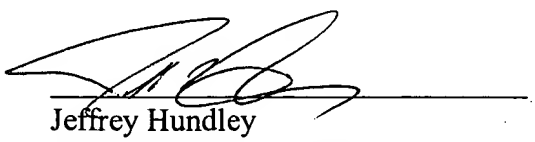
The applicants' disclosure more than adequately meets this burden. The presently claimed invention is directed to the applicants' discovery that SEQ ID NO: 392 is expressed in ovary tumor tissue but is not expressed in normal ovary tissue. This single identifying feature of the claimed invention, *i.e.*, ovary tumor-specificity, is common among the subject matter now claimed, and, furthermore, has been specifically incorporated into newly added claims 74-77. Thus, the applicants' disclosure clearly identifies a sufficient, relevant, identifying characteristic that would lead the skilled artisan to recognize that the applicants were indeed in possession of the presently claimed invention at the time this application was filed. Favorable consideration of the newly added claims is respectfully requested.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned **"Version With Markings to Show Changes Made."**

Favorable reconsideration and allowance of the currently pending claims is respectfully solicited. The Examiner is invited to contact the undersigned at (206) 694-4885 with any questions, comments and/or suggestions pertaining to this communication.

Respectfully submitted,

SEED Intellectual Property Law Group PLLC



Jeffrey Hundley
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Enclosure:
Declaration of Gary R. Fanger, Ph.D.

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Specification:

Page 6, lines 14-23, have been amended as follows:

Figure 10 ~~depicts results~~is a chart that depicts results of microarray expression analysis of the ovarian carcinoma sequence designated 3f.

Figure 11 is a chart that depicts results ~~depicts results~~ of microarray expression analysis of the ovarian carcinoma sequence designated 6b.

Figure 12 is a chart that depicts results ~~depicts results~~ of microarray expression analysis of the ovarian carcinoma sequence designated 8e.

Figure 13 is a chart that depicts results ~~depicts results~~ of microarray expression analysis of the ovarian carcinoma sequence designated 12c.

Figure 14 is a chart that depicts results ~~depicts results~~ of microarray expression analysis of the ovarian carcinoma sequence designated 12h.

In the Claims:

Claims 1, 2, 9-12, 21, 23, 24, and 69 have been canceled.

Claims 73-81 have been added.

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